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K032688

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510(k) SUMMARY

Sightline Technologies' ColonoSight Model 510B

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Sightline Technologies Ltd.
Advanced Technology Center
31905 Haifa
ISRAEL

Phone: +972-4-855-0447
Facsimile: +972-4-855-0164

Contact Person: Sharon Goldfarb-Albak

Date Prepared:

Name of Device and Name/Address of Sponsor

ColonoSight Model 510B

Sightline Technologies Ltd.
Advanced Technology Center
31905 Haifa
ISRAEL

Phone: +972-4-855-0447
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Common or Usual Name

Colonoscope and Accessories

Classification Name

Colonoscope and Accessories

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Predicate Devices

Pentax Video Colonoscopes (K961570, K961563, and K951579).
EndoSheath® (K990354, K012543, and K021344),
with VSI C-F100 Colonoscope (K943895),
Sightline RectoSight (K994130, K011782).

Intended Use

The ColonoSight Model 510B is intended to provide visualization (via a video monitor) and therapeutic access to the lower gastrointestinal tract. The lower gastrointestinal tract includes, but is not restricted to, the organs, tissues, and subsystems of the large bowel. The device is introduced rectally as with any standard colonoscope, when indications consistent with the requirement for the procedure are observed in adult patient populations.

Technological Characteristics and Substantial Equivalence

The ColonoSight is a colonoscope covered with a disposable protective sheath and incorporating disposable channels for insufflation, irrigation and suction/therapeutic interventions. Intubation is perfomed using an "air assisted push technology". The main components are: EndoSight, Camera Contol Unit, Hydro-pneumatic Control Unit; disposable ColonoSleeve and disposable Hub.

The ColonoSight is substantially equivalent to the other currently marketed Colonoscopes which are referenced above. The ColonoSight and its predicate devices are Colonoscopes. Thus, the ColonoSight raises no new issues of safety or effectiveness.

Performance Data

Microbiological barrier bench tests were performed on the ColonoSleeve component both in a laboratory and in animals. The ColonoSight system was tested for funtionality. Optical Perfomance tests were performed both with and without the disposable components. Biocompatibility and pyrogenicity tests were performed. In addition, clinical trials were performed with no recorded complications. In all instances, the ColonoSight functioned as intended and performed as expected.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 5 2004

Sightline Technologies, Ltd.
c/o Jonathan S. Kahan
Hogan & Hartson L.L.P.
Columbia Square
555 Thirteenth Street, N.W.
WASHINGTON DC 20004-1109

Re: K032688
Trade/Device Name: ColonoSight® Model 510B
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Codes: 78 FDF and KOG
Dated: November 24, 2003
Received: December 8, 2003

Dear Mr. Kahan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K032688

Device Name: ColonoSight Model 510B

Indications for use: The ColonoSight provides visualization and therapeutic access to the lower gastrointestinal tract. Visualization is provided via a video monitor. The lower gastrointestinal tract includes, but is not restricted to, the organs, tissues, and subsystems of the large bowel. The device is introduced rectally as with any standard colonoscope, when indications consistent with the requirement for the procedure are observed in adult patient populations.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDE)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ Or Over-The-Counter Use____
(Per 21 C.F.R. 801.109) (Optional Format 1-2-96)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K032688